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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,574	01/16/2001	Jean-Christophe Francis Audonnet	454313.3154.1	2896

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/760,574	AUDONNET ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *84-118* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *84-118* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 11/03/04. Claims 84-114 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 11/3/04 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Double Patenting

Claims 84, 85, 96 and 116-117 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8 of U.S. Patent No. 6,376,473 B1 (Audonnet) in view of in view of Klavinskis et al. (J. Immunol. Vol. 162, No. 1, pages 254-262; January 1, 1999) for the reasons of record.

Claims 84-91 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8 of U.S. Patent No. 6,376,473 B1 (Audonnet) in view of Klavinskis et al. (J. Immunol. Vol. 162, No. 1, pages 254-262; January 1,

1999) and further in view of Xiang et al. (Immunity 1995, 2:129-135), and Baker et al. (US Patent 5,106,733; 1992) for the reasons of record.

Claims 84, 92, 94, 95, 100 and 108 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8 of U.S. Patent No. 6,376,473 B1 (Audonnet) in view of Klavinskis et al. (J. Immunol. Vol. 162, No. 1, pages 254-262; January 1, 1999) and further in view of Li (WO 96/40945) for the reasons of record.

Claims 84, 93, 97, 98 and 104 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8 of U.S. Patent No. 6,376,473 B1 (Audonnet) in view of Klavinskis et al. (J. Immunol. Vol. 162, No. 1, pages 254-262; January 1, 1999) and further in view of Choi et al. (Virology 1998, 250:230-240) for the reasons of record.

Claims 84-118 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8 of U.S. Patent No. 6,376,473 B1 (Audonnet) in view of Klavinskis et al. (J. Immunol. Vol. 162, No. 1, pages 254-262; January 1, 1999) and further in view of Xiang et al. (Immunity 1995, 2:129-135), Baker et al. (US Patent 5,106,733; 1992), Li (WO 96/40945), and Choi et al. (Virology 1998, 250:230-240) for the reasons of record.

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Response to the Applicants arguments appear below.

Claim Rejections - 35 USC § 103

Claims 84, 85, 96 and 116-118 are rejected under 35 U.S.C. 103(a) as being obvious over claims 5-8 of U.S. Patent No. 6,376,473 B1 (Audonnet) in view of in view of Klavinskis et al. (J. Immunol. Vol. 162, No. 1, pages 254-262; January 1, 1999) for the reasons of record.

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Claims 84-118 are rejected under 35 U.S.C. 103(a) as being obvious over claims 5-8 of U.S. Patent No. 6,376,473 B1 (Audonnet) in view of Klavinskis et al. (J. Immunol. Vol. 162, No. 1, pages 254-262; January 1, 1999) and further in view of Xiang et al. (Immunity 1995, 2:129-135), Baker et al. (US Patent 5,106,733; 1992), Li (WO 96/40945), and Choi et al. (Virology 1998, 250:230-240) for the reasons of record.

Response to Arguments

Applicant's arguments filed 11/03/04 have been fully considered but they are not persuasive.

It is noted that this response section addresses Applicants arguments for all of the pending rejections.

Applicants direct the Examiner to a review article ("Babiuk"), which has been considered by the Examiner. Applicants argue that Babiuk summarizes the state of the art of DNA immunization of livestock and assert that Babiuk indicates that DNA immunization, although extremely successful in mice, significant barriers still exist in immunizing large animals and humans with DNA vaccines (see p. 5, first paragraph).

In response, it is acknowledged that Babiuk is a review article that summarizes the state of the art of DNA immunization. However, it is respectfully pointed out that Babiuk was published in 2004, several years after the effective filing date of the instant application. Furthermore, with respect to the use of DMRIE-DOPE in DNA vaccines, the articles which Babiuk refers to (i.e., the pony and dog experiments) were also after the filing date of the instant application. It is respectfully pointed out that the determination of obviousness is at the time of filing (See MPEP). Since the pertinent references reviewed by Babiuk were after the filing of the instant application, Babiuk is not considered to be the state of the art at the time of filing. Furthermore, with respect to DNA vaccines, Babiuk speaks of DNA vaccines in general and does not explicitly indicate that the specific bovine DNA vaccine of the '473 patent would not work in bovines. In fact, contrary to the generalizations of Babiuk the '473 patent teaches a specific

bovine DNA vaccine and teaches that the vaccine can successfully vaccinate bovines. Surely Babiuk does not question the effectiveness of the '473 bovine DNA vaccine.

The Applicants also argue that if it would have been obvious to one of ordinary skill in the art to combine a bovine DNA vaccine with a lipid, there would have been more than two studies (see p. 5, third paragraph).

In response, the number of post filing studies the have been performed is inconsequential with respect to obviousness. Furthermore, the fact that at least two studies have been performed appears to support the Office's position of obviousness.

The Applicants also argue that the '409 patent relates to an adjuvant composition comprising GAP-DMORIE and that one of ordinary skill in the art would not recognize that all cationic lipids are effective adjuvants. Applicants also assert that the '409 patent admits that not all cationic lipids are recognized as useful as effective adjuvants. Applicants also assert the '409 patent indicates that "there probably is probably no CTL response with DMRIE (see p. 6, second paragraph). Furthermore, Applicants refer to the '131 patent as indicating that although DMRIE has been demonstrated to facilitate the entry of biologically active molecules into cells the uptake efficiency are insufficient to support numerous therapeutic applications and that DMRIE also results in low in vivo expression (see p. 6, third and fourth paragraphs). Applicants also argue that there must be some desirability in the art to modify reference teachings to arrive at an invention and assert that in the instant case there is no teaching, suggestion, incentive or motivation to modify the cited references to arrive at the claimed invention (see p. 7, first paragraph).

In response, Applicants appear to be arguing against DMRIE's ability to act as an adjuvant and to facilitate delivery of a therapeutic molecule. However, it is respectfully pointed out that the broadest claims are not limited to DMRIE. Furthermore, the '409 patent clearly indicates that a lipid, such as one encompassed by the formula of claim 1, can be an effective adjuvant useful in vertebrate DNA vaccines. As indicated in the precious Office Action, the '409 patent teaches, "the adjuvant composition of the instant invention enhances the immune response of the vertebrate to the immunogen." (emphasis added, see col. 2, lines 55-61). Therefore, there is a motivation and expectation of success for for using the lipid of the '409 patent in combination with the bovine DNA vaccine of the '473 patent. With respect to applicants assertion that there is probably no CTL response with DMRIE, it is respectfully pointed out that the '409 patent does not explicitly make such an assertion, and applicants arguments are merely conjecture that are not supported by evidence. Furthermore, it is respectfully pointed out that the '409 patent does not teach that lipids can not deliver therapeutic molecules to cells or that lipids do not enhance the immune response. To the contrary, the '409 patent indicates that the lipid can effectively enhance the immune response to an immunogen and that lipids can deliver therapeutic molecules to cells, thus providing motivation and an expectation of success to use a lipid in combination with a DNA vaccine.

The Applicants also direct the Examiner to Example 17 of WO 01/5288 which compares neutralizing antibody response of cattle vaccinated with a plasmid vaccine alone and in combination with DMRIE-DOPE. Applicants assert that the teaching that DMRIE-DOPE significantly enhances the neutralizing antibody response and thus indicates that using DMRIE-DOPE has "surprisingly superior results" compared to the DNA vaccine alone.

In response, it is acknowledged that the Example indicates that DMRIE-DOPE significantly enhances the neutralizing antibody response. However, the Examiner respectfully points out that a superior result is suggested by the art of record, thus the result disclosed in WO 01/5288 is not an unexpected result.

In summary, the prior art teaches a bovine DNA vaccine (the '473 patent) and the use of a lipid (including DMRIE-DOPE) in combination with a DNA vaccine (the '409 patent and Klavinskis) and teaches that the lipid can enhance the effectiveness often DNA vaccine, as indicated in the previous Action. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of filing to combine the teachings of the indicated references to make the claimed invention with a reasonable expectation of success. Applicants arguments have been fully considered but are not persuasive. As such, the claims remain rejected for the reasons of record.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art unit 1635

DAVE TRONG NGUYEN
PRIMARY EXAMINER